510(k) Summary of Safety and Effectiveness

OCT 10 2012

Submitted by:	United Orthopedic Corporation
Address:	No 57, Park Ave 2, Science Park, Hsinchu 300, Taiwan
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Date of Summary:	August 14, 2012
Contact Person	Fang-Yuan Ho Regulation and Document Management
Proprietary Name:	Femoral Heads, +2.5 and +7.5 mm Offset
Common Name:	Femoral Head Prosthesis
Device Classification Name and Reference:	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis per 21CFR 888.3358 This falls under the Orthopedics panel.
Device Class	Class II
Panel Code	Orthopaedics Device
Device Product Code:	LPH
Predicate Device:	1. "UNITED" U2 Acetabular Cup and Femoral Head (K022520) 2. "UNITED" U2 Hip System (K111546)

Device Description:

This device manufactured from CoCrMo alloy (ASTM F1537) is an extension of cleared "UNITED" U2 Acetabular Cup and Femoral Head (K022520) and "UNITED" U2 Hip System (K111546). The material, design, safety and effectiveness of this subject are identical to the previously cleared femoral heads except for its offset. The previously cleared femoral head offsets for the U2 Hip System are -3, +0, +5, and +10 mm. This submission adds +7.5 and +2.5 mm offset heads for 28, 32 and 36 mm

diameter sizes. This device is intended to be used with the previously cleared U2 Acetabular Cup Liner (K050262), U2 XPE Liner (K111546), U2 bipolar implant (K101670), Revision Stem (K062978), HA/Ti Plasma Spray Stem (K003237), Ti Porous Coated Stem (K003237), UTF Stem (K110245), Press-fit Stem (K111546) and Cemented Stem (K111546) in corresponding size. The differences of femoral head offset do not affect the intended use of the device or alter the fundamental scientific technology of the device.

Indications:

This device is indicated in hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

For use as a Total Hip Replacement

1. Painful, disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis.
2. Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure.
3. Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

For use as a Bipolar Hip Replacement

1. Femoral head/neck fractures or non-unions.
2. Aseptic necrosis of the femoral head.
3. Osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal acetabular involvement or distortion.

Cemented stem is designed for cemented use only.

Basis for Substantial Equivalence:

The safety and effectiveness of the subject device are substantially equivalent to the

previously cleared "UNITED" Femoral Head (K022520, K111546), except for an increasing in the offset type. The modifications do not change the indications or fundamental scientific technology.

Performance Data:

This 510(k) submission was prepared in accordance with the Agency's, "Class II Special Controls Guidance Document- Hip Joint Metal Polymer Constrained Cemented or Uncemented Prosthesis" and "Guidance Document for Testing Non-Articulating, 'Mechanically Locked', Modular Implant Components". Femoral Head Disassembly loads for the stems, completed as part of the design assurance process, demonstrated that this device is safe and effective and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 10 2012

United Orthopedic Corp.
% Ms. Fang-Yuan Ho, Regulation and Document Specialist
No 57, Park Ave 2
Science Park, Hsinchu 300
Taiwan

Re: K122504
Trade/Device Name: Femoral Heads, 2.5 and 7.5mm Neck Length
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated
Regulatory Class: II
Product Code: LPH
Dated: August 14, 2012
Received: August 16, 2012

Dear Ms. Ho:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

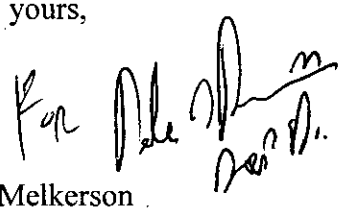
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510 (k) Number (if known): K122504

Device Name: Femoral Heads, +2.5 and +7.5 mm Offset

Indications for Use:

This device is indicated in hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

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Cemented stem is designed for cemented use only.

Prescription Use x AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K122504